



# Predicting venous thromboembolism following laparoscopic bariatric surgery: development of the *BariClot* tool using the MBSAQIP database

Jerry T. Dang<sup>1,4</sup>  · Noah Switzer<sup>1</sup> · Megan Delisle<sup>2</sup> · Michael Laffin<sup>1</sup> · Richdeep Gill<sup>3</sup> · Daniel W. Birch<sup>1</sup> · Shahzeer Karmali<sup>1</sup>

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## Abstract

**Background** Bariatric surgery is an effective treatment for severe obesity; however, postoperative venous thromboembolism (VTE) remains a leading cause of morbidity and mortality. The objective of this study is to develop a tool to stratify individuals undergoing laparoscopic bariatric surgery according to their 30-day VTE risk.

**Methods** This is a retrospective cohort study of the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) database. This registry collects data specific for metabolic or bariatric surgery with 30-day outcomes from 791 centers. Individuals undergoing primary laparoscopic Roux-en-Y gastric bypass (LRYGB) or laparoscopic sleeve gastrectomy (LSG) were included. Characteristics associated with 30-day VTE were identified using univariate and multivariable analyses. A predictive model, *BariClot*, was derived from a randomly-generated derivation cohort using a forward selection algorithm. *BariClot*'s robustness was tested against a validation cohort of subjects not included in the derivation cohort. The calibration and discrimination of two previously published VTE risk tools were assessed in the MBSAQIP population and compared to *BariClot*.

**Results** A total of 274,221 patients underwent LRYGB or LSG. Overall, 1106 (0.4%) patients developed VTE, 452 (0.2%) developed pulmonary embolism, and 43 (0.02%) died due to VTE. VTE was the most commonly identified cause of 30-day mortality. A prediction model to assess for risk of VTE, *BariClot*, was derived and validated. *BariClot* consists of history of VTE, operative time, race, and functional status. It stratifies individuals into very high (> 2%), high (1–2%), medium (0.3–1%), and low risk groups (< 0.3%). This model accurately predicted events in the validation cohort and outperformed previously published scoring systems.

**Conclusions** *BariClot* is a predictive tool that stratifies individuals undergoing bariatric surgery based on 30-day VTE risk. Stratifying low- and high-risk populations for VTE allows for informed clinical decision-making and potentially enables further research on customized prophylactic measures for low- and high-risk populations.

**Keywords** Bariatric surgery · Venous thromboembolism · Deep vein thrombosis · Pulmonary embolism · Sleeve gastrectomy · Roux-en-Y gastric bypass

Bariatric surgery is an effective treatment for severe obesity [1] and 74.4% of index bariatric surgical procedures are either laparoscopic Roux-en-Y gastric bypass (LRYGB) or

laparoscopic sleeve gastrectomy (LSG) [2]. Although modern bariatric surgery has an excellent safety profile, venous thromboembolism (VTE) remains a significant cause of morbidity and mortality [3]. Bariatric surgery patients are considered high risk for the development of VTE due to obesity [4]. Obesity reduces mobility and leads to conditions associated with VTE such as hypertension, diabetes, venous stasis, and obstructive sleep apnea [5, 6]. Clinically significant VTE, which includes deep venous thrombosis (DVT) and pulmonary embolism (PE), occur in 0.2–3.5% of

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✉ Jerry T. Dang  
dang2@ualberta.ca

Extended author information available on the last page of the article

patients after bariatric surgery [7–14] and pulmonary embolism remains a leading cause of mortality [15].

Due to this risk, the American Society for Metabolic and Bariatric Surgery (ASMBS) recommends mechanical prophylaxis or chemoprophylaxis for all subjects undergoing bariatric surgical procedures. The ASMBS states that mechanical prophylaxis may be adequate in low risk patients (<0.4% risk) but recommends a combination of both mechanical and chemoprophylaxis in higher risk patients [16]. Currently available prediction tools have limited application in determining a patient's VTE risk profile, making these recommendations difficult to implement [17, 18].

Predictive tools in surgery have become increasingly relevant given the emphasis placed on shared decision-making and informed consent. The Caprini VTE risk score [18, 19] is widely used to determine the risk of VTE after a surgical procedure, and in 2012 Finks et al. developed the Michigan Bariatric Surgery Collaborative (MBSC) VTE risk calculator to predict VTE risk specifically after bariatric surgery [17]. Both of these tools present issues, as Caprini is a general use tool and may not be applicable to the bariatric surgical population, and the MBSC tool may only be applicable to a regional population. Furthermore, the MBSC tool was derived from a database with a low number of VTE events ( $n=93$ ), and their derivation relied upon bootstrap resampling, rather than with validation from a separate set of individuals. The Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) database collects clinically rich data from 791 bariatric surgery centers, capture approximately 95% of all bariatric procedures performed in the United States, and offers the opportunity to develop a more widely applicable and effective clinical tool to predict the risk of venous thromboembolism after bariatric surgery [20].

The primary objective of this study was to identify factors associated with VTE within 30 days of bariatric surgery. The secondary aim was to develop a clinically useful tool to predict the probability of 30-day VTE after LRYGB or LSG.

## Materials and methods

### Data source

Data were combined from the 2015 and 2016 MBSAQIP participant use files. The data registry collects prospective, risk-adjusted data, based on standardized definitions for preoperative, intraoperative, and postoperative variables that are specific for metabolic and bariatric surgery [20]. Data are abstracted by trained metabolic and bariatric surgical clinical reviewers at each site who are regularly audited for accuracy.

### Study population

This study included only patients who underwent LRYGB or LSG as these are the two main procedures performed worldwide for the treatment of obesity [2]. Other bariatric procedures were excluded. The study population also excluded patients who were under 18 years of age, undergoing revisional bariatric surgery, had previous bariatric or foregut surgery, and undergoing emergency surgery.

### Patient variables

Basic demographic data included age, sex, race, and body mass index (BMI). Patient comorbidities included the following: hypertension, gastroesophageal reflux disease, type 2 diabetes, hyperlipidemia, venous stasis, renal insufficiency, dialysis dependency, chronic obstructive pulmonary disease, sleep apnea, oxygen dependency, chronic steroid use, smoking, and preoperative therapeutic anticoagulation use. Patient history included previous myocardial infarction, previous VTE, previous major cardiac surgery, and previous percutaneous coronary interventions. Functional status variables included preoperative functional status and American Society of Anesthesiologists (ASA) Physical Status classification.

### Outcome variables

The primary outcome of interest was 30-day VTE. VTE was defined as a composite endpoint in the database as any patient who had any of the following:

- DVT or PE confirmed on imaging requiring anticoagulation therapy
- DVT or PE confirmed during autopsy
- Reoperation for DVT or PE
- Readmission for DVT or PE
- Reintervention for DVT or PE
- Death due to DVT or PE

This definition of VTE does not include patients who were treated empirically for suspected VTE without confirmation on imaging or by autopsy. Secondary outcomes included anastomotic leak, significant postoperative bleeding, reoperation, postoperative intervention, and mortality within 30 days.

Descriptive analysis was also performed on inferior vena cava (IVC) filters and their impact on VTE and mortality.

### Statistical analysis

Statistical analysis was performed using Stata 14.2 [21]. Descriptive categorical data were expressed as percentages and continuous data were expressed as weighted

mean  $\pm$  standard deviation (SD). Baseline differences between groups were evaluated by univariate analyses using chi-squared for categorical data and independent sample *t* test for continuous data. Univariate logistic regression was used to compare differences between patients who developed VTE and those who did not.

Multivariable logistic regression analysis was used to determine predictive factors for the development of VTE within 30 days. The available case method was used to handle missing data as all variables had less than 5% missingness. Patient factors and operative time were included in the model. Any variable with a *p* value  $< 0.05$  in univariate analysis was included in multivariable analysis. Variables were then checked for clinically important interactions for potential inclusion in the model. Major complications including anastomotic leak and postoperative bleeding were excluded from the model as these occur after surgery and would not be useful as predictors of VTE.

Multivariable logistic regression was also performed to determine if VTE was an independent risk factor for 30-day mortality. This model included patient factors, operative time, anastomotic leaks, and postoperative bleeding.

### Predictive model

A derivation and validation cohort were randomly generated. Variables with *p* value  $< 0.05$  in univariate analysis were included in the predictive model. A forward selection algorithm with an entry *p* value of  $< 0.01$  was used to build a logistic regression model predicting probability of VTE within 30 days using the derivation data set. The area under the receiver operating characteristic (AUROC) curve was calculated for the derivation and validation dataset. The Hosmer–Lemeshow goodness of fit test was used to assess calibration in the validation dataset.

### Comparing predictive tools

The probability of developing a VTE was calculated using the prediction tools developed by Finks et al. [17] and Caprini et al. [18, 19] and tested against the entire MBSA-QIP dataset. Predicted probabilities were compared to observed rates of VTE by pre-defined risk categories in Caprini's model. The MBSC tool did not categorize patients into risk categories, so deciles were used. Calibration was assessed for both prediction tools using the Hosmer–Lemeshow goodness-of-fit test. The AUROC curves for the three predictive tools were tested for equality and a two-tailed *p* value  $< 0.05$  was considered significant [22].

## Results

A total of 274,221 patients underwent LRYGB or LSG at 791 centers. Of these patients, 196,625 (71.7%) underwent LSG and 77,596 (28.3%) underwent LRYGB. Patient baseline demographics are summarized in Table 1. 1106 (0.4%) patients developed any form of VTE, and 452 (0.2%) developed pulmonary embolism. Mortality was attributed to VTE in 43 (0.02%) patients, making VTE the most commonly identified cause of death (19.3% of 30-day mortality) in patients undergoing laparoscopic bariatric surgery.

### Factors associated with VTE after laparoscopic bariatric surgery

The characteristics of individuals who developed VTE and those who did not are summarized in Table 1. The development of VTE did not differ between those undergoing LRYGB and LSG (0.4 vs. 0.4%, *p* = 0.686) (Table 2). Operative time was significantly associated with the development of VTE between groups (*p*  $< 0.001$ ). Patients who developed a postoperative anastomotic leak or bleed and those who required postoperative intervention or reoperation were more likely to develop VTE (*p*  $< 0.001$ ).

Following adjustment using multivariable logistic regression, six variables were independently predictive of 30-day VTE: previous VTE (OR 4.70, 95% CI 3.77–5.87, *p*  $< 0.001$ ), male sex (OR 1.16, 95% CI 1–1.34, *p* = 0.049), black race (OR 1.59, 95% CI 1.38–1.83, *p*  $< 0.001$ ), poor preoperative functional status (OR 1.44, 95% CI 1.06–1.94, *p* = 0.019), higher BMI (OR 1.10, 95% CI 1.02–1.17, *p* = 0.008), and increasing operative time (OR 1.20, 95% CI 1.13–1.27, *p*  $< 0.001$ ) (Table 3).

VTE was associated with the largest odds of death (OR 40.0, 95% CI 28.5–56.2, *p*  $< 0.001$ ) (Table 4), surpassing anastomotic and staple line leak (OR 6.6, 95% CI 3.8–11.5, *p*  $< 0.001$ ) and postoperative bleeding (OR 3.7, 95% CI 2.4–5.8, *p*  $< 0.001$ ).

### IVC filter use is associated with mortality in laparoscopic bariatric surgical patients

A total of 2364 patients had IVC filters which were pre-existing in 629 patients and placed prophylactically for bariatric surgery in 1703 patients (unknown in 32 patients). Patients with IVC filters had a higher percentage of PE (0.42 vs. 0.16%, *p* = 0.002). In patients with IVC filters placed in anticipation for bariatric surgery, the rates of PE were still higher in the IVC cohort but not statistically significant (0.25 vs. 0.16, *p* = 0.486). Patients

**Table 1** Patient characteristics

	No VTE <i>n</i> = 273,115	VTE <i>n</i> = 1106	<i>p</i> Value
Age, years			0.084
Mean ± SD	44.6 ± 12.0	45.5 ± 11.8	
18–29	31,134 (99.7)	103 (0.3)	
30–39	69,053 (99.6)	263 (0.4)	
40–49	79,106 (99.6)	345 (0.4)	
50–59	61,690 (99.6)	253 (0.4)	
≥ 60	32,132 (99.6)	142 (0.4)	
% Female	79.2	75.5	0.003
Race			< 0.001
White	201,596 (99.6)	755 (0.4)	
Black or African American	47,092 (99.4)	278 (0.6)	
Other	24,427 (99.7)	73 (0.3)	
BMI			< 0.001
Mean ± SD	45.5 ± 8.0	46.8 ± 9.4	
< 35	8999 (99.6)	35 (0.4)	
35–39	60,084 (99.7)	209 (0.3)	
40–50	138,970 (99.6)	542 (0.4)	
50–59	48,642 (99.5)	222 (0.5)	
60–69	11,147 (99.4)	63 (0.6)	
≥ 70	3219 (99.2)	27 (0.8)	
Functional status			0.001
Independent	270,359 (99.6)	1085 (0.4)	
Partially dependent	1834 (99.5)	10 (0.5)	
Fully dependent	922 (98.8)	11 (1.2)	
ASA class			0.031
1–2	63,353 (99.6)	233 (0.4)	
3	198,653 (99.6)	801 (0.4)	
4–5	9879 (99.5)	54 (0.5)	
Smoking status			< 0.916
No	249,162 (99.6)	1010 (0.4)	
Yes	23,953 (99.6)	96 (0.4)	
Diabetes			0.745
No	200,248 (99.6)	822 (0.4)	
Non-insulin dependent	48,686 (99.6)	191 (0.4)	
Insulin dependent	24,181 (99.6)	93 (0.4)	
Hypertension			0.516
No	139,474 (99.6)	554 (0.4)	
Yes	133,641 (99.6)	552 (0.4)	
GERD			0.082
No	188,121 (99.6)	735 (0.4)	
Yes	84,994 (99.6)	371 (0.4)	
COPD			0.031
No	268,294 (99.6)	1077 (0.4)	
Yes	4821 (99.4)	29 (0.6)	
Hyperlipidemia			0.569
No	205,744 (99.6)	825 (0.4)	
Yes	67,371 (99.6)	281 (0.4)	
Chronic steroids			0.138
No	268,723 (99.6)	1082 (0.4)	
Yes	4392 (99.5)	24 (0.5)	

**Table 1** (continued)

	No VTE <i>n</i> = 273,115	VTE <i>n</i> = 1106	<i>p</i> Value
Renal insufficiency			0.077
No	271,326 (99.6)	1094 (0.4)	
Yes	1789 (99.3)	12 (0.7)	
Dialysis dependent			0.112
No	272,333 (99.6)	1100 (0.4)	
Yes	782 (99.2)	6 (0.8)	
History of VTE			<0.001
No	265,601 (99.6)	960 (0.4)	
Yes	7514 (98.0)	146 (2.0)	
Preoperative therapeutic anticoagulant use			<0.001
Yes	266,522 (99.6)	1031 (0.4)	
No	6593 (98.9)	75 (1.1)	
Venous stasis			<0.001
No	270,282 (99.6)	1081 (0.4)	
Yes	2833 (99.1)	25 (0.9)	
Oxygen-dependent			0.933
No	271,197 (99.6)	1098 (0.4)	
Yes	1918 (99.6)	8 (0.4)	
Sleep apnea			<0.001
No	169,675 (99.6)	625 (0.4)	
Yes	103,440 (99.5)	481 (0.5)	
History of MI			0.263
No	269,479 (99.6)	1087 (0.4)	
Yes	3636 (99.5)	19 (0.5)	
Previous major cardiac surgery			0.009
No	269,988 (99.6)	1084 (0.4)	
Yes	3127 (99.3)	22 (0.7)	
Previous PCI			0.010
No	267,299 (99.6)	1070 (0.4)	
Yes	5816 (99.4)	36 (0.6)	

ASA American Society of Anesthesiologists, *BMI* body mass index, *COPD* chronic obstructive pulmonary disease, *VTE* venous thromboembolism, *GERD* gastroesophageal reflux disease, *MI* myocardial infarction, *PCI* percutaneous coronary intervention

with IVC filters also had higher mortality (0.42 vs. 0.10%,  $p < 0.001$ ).

### The BariClot tool to predict VTE risk outperforms existing VTE risk prediction tools

A derivation ( $n = 137,124$ ) and validation ( $n = 137,097$ ) cohort were randomly generated. A forward regression was performed to generate the *BariClot* prediction model:

$$\text{Total score} = [9 \times \text{previous VTE}] + [\text{operative time in hours}] + [3 \times \text{black race}] + [3 \times \text{preoperative functional status score}]$$

Low risk was defined as a score  $< 1$  corresponding to a risk of less than 0.3%, medium risk included scores  $\geq 1$  and  $< 7$  corresponding to a risk of 0.3–1.0%, high risk included

scores  $\geq 7$  and  $< 10$  corresponding to a risk of 1.0–2.0%, and very high risk included scores  $\geq 10$  corresponding to a risk of  $> 2.0\%$  (Fig. 1).

The AUROC curve in the derivation dataset was 0.61 and 0.59 in the validation dataset (Fig. 2). The optimism was 1%. The prediction tool demonstrated good calibration in the validation dataset ( $p = 0.51$ ). Using a cutoff of 1% to define high risk patients, the sensitivity was 14.6% and the specific-

ity was 97.3%. The positive predictive value was 2.1% and the negative predictive value was 99.7%.

Our tool was compared to Caprini's risk tool [19] and the MBSC tool [17]. Both demonstrated poor calibration with

**Table 2** Perioperative and postoperative factors

	No VTE <i>n</i> =273,115	VTE <i>n</i> =1106	<i>p</i> Value
<b>Procedure</b>			
Roux-en-Y gastric bypass	77,277 (99.6)	319 (0.4)	0.686
Sleeve gastrectomy	195,838 (99.6)	787 (0.4)	
<b>Operative time, minutes</b>			
Mean ± SD	86.6 ± 46.9	96.7 ± 59.8	<0.001
0–59.9	84,899 (99.6)	313 (0.4)	
61–119.9	135,725 (99.6)	522 (0.4)	
120–179.9	40,441 (99.6)	175 (0.4)	
180–239.9	8776 (99.3)	60 (0.7)	
240–299.9	2112 (99.1)	18 (0.9)	
<i>d</i> > 300	1162 (98.5)	18 (1.5)	
<b>Anastomotic leak</b>			
No	271,858 (99.6)	1069 (0.4)	<0.001
Yes	1257 (97.1)	37 (2.9)	
<b>Bleed</b>			
No	270,614 (99.6)	1046 (0.4)	<0.001
Yes	2501 (97.7)	60 (2.3)	
<b>Reoperation</b>			
No	269,820 (99.6)	974 (0.4)	<0.001
Yes	3295 (96.1)	132 (3.9)	
<b>Postoperative intervention</b>			
No	269,353 (99.7)	925 (0.3)	<0.001
Yes	3762 (95.4)	181 (4.6)	

VTE venous thromboembolism

**Table 3** Significant risk factors for venous thromboembolism on multivariable logistic regression

Risk factor	Adjusted odds ratio <sup>a</sup>	95% confidence interval	<i>p</i> Value
Previous venous thromboembolism	4.70	3.77–5.87	<0.001
Male sex	1.16	1.00–1.34	0.049
Black race (compared with White)	1.59	1.38–1.83	<0.001
Poor preoperative functional status	1.44	1.06–1.94	0.019
Higher body mass index	1.10	1.02–1.17	0.008
Longer operative time	1.20	1.13–1.27	<0.001

<sup>a</sup>Adjusted for sex, race, body mass index, preoperative functional status, American Society of Anesthesiologists Physical Status classification, chronic obstructive pulmonary disease, history of venous thromboembolism, preoperative therapeutic anticoagulation use, venous stasis, sleep apnea, previous major cardiac surgery, and previous percutaneous coronary intervention

the observed probability of VTE ( $p < 0.01$ ) (Supplementary Table S1 and Supplementary Table S2). The AUROC of Caprini's tool was 0.55 and the MBSC tool was 0.58 while the *BariClot* tool was 0.60 (Fig. 3). On direct comparison, the *BariClot* tool had better predictability than both tools ( $p < 0.001$ ).

## Discussion

This study utilized the largest available prospective bariatric surgical database to characterize the risk factors associated with the development of VTE within 30 days of surgery and derive a prediction model to stratify individual risk of 30-day VTE. The incidence of VTE was consistent with previously published literature at 0.4 percent but was responsible for approximately a fifth of all mortality. Several risk factors were identified to be associated with VTE, most notably the history of a previous VTE. Other associated factors included male sex, black race, poor functional status, higher BMI, and longer operative time. These predictive factors are consistent with other studies [8, 17].

The pathogenesis of DVT was originally described by Virchow in 1856, and the paradigm of VTE being multifactorial in nature persists [24]. Typically, there is an underlying hypercoagulability, which can be due to a pre-existing genetic factor or an acquired risk factor. The finding that previous VTE is associated with a much greater risk of a repeat VTE after bariatric surgery is unsurprising, as these individuals likely suffer from a relatively hypercoagulable state at baseline. Venous stasis is promoted by prolonged operating time, and decreased functional status, promoting venous thrombi to form in areas of slow blood flow. The third factor classically associated with VTE is endothelial vessel wall damage, which occurs with surgery, and activates von Willebrand's factor and platelet aggregation, further promoting thrombosis formation [25]. Once this thrombus has formed, typically in the deep venous system of the lower extremities, it can migrate into the pulmonary system resulting in PE.

Racial elements were associated with VTE risk, specifically black individuals were found to have an increased risk of postoperative VTE. This is consistent with studies that demonstrate a higher risk and incidence of VTE in blacks compared to whites [26–29]. This increased risk is thought to be primarily due to genetic factors, though some suggest that factors including a higher BMI and higher proportion of VTE-associated diseases such as hypertension and diabetes in this population, are responsible for this risk [30].

Here we present *BariClot*, a tool to predict a patient's probability of 30-day VTE. Stratifying a patient's VTE risk can help clinicians in informing patients about their risk of postoperative VTE and in choosing appropriate VTE

**Table 4** Significant risk factors for 30-day mortality on multivariable logistic regression

Risk factor	Adjusted odds ratio <sup>a</sup>	95% confidence interval	p Value
<b>Patient factors</b>			
Older age	1.04	1.03–1.06	<0.001
Higher body mass index	1.05	1.04–1.06	<0.001
Male sex	1.68	1.29–2.19	<0.001
Black race (vs. White ethnicity)	1.79	1.34–2.40	<0.001
Type 2 diabetes	1.25	1.05–1.47	0.011
Chronic obstructive pulmonary disease	2.16	1.35–3.45	0.001
Hyperlipidemia	1.45	1.09–1.94	0.012
Dialysis-dependent	4.44	1.82–10.9	0.001
Preoperative therapeutic anticoagulation	2.33	1.56–3.47	<0.001
<b>Operative and postoperative factors</b>			
Roux-en-Y gastric bypass (vs. sleeve gastrectomy)	1.38	1.05–1.81	0.020
Longer operative time	1.17	1.04–1.33	0.011
Postoperative venous thromboembolism	40.0	28.5–56.2	<0.001
Anastomotic or staple line leak	6.64	3.82–11.5	<0.001
Postoperative bleeding	3.72	2.36–5.84	<0.001

<sup>a</sup>Adjusted for age, body mass index, sex, race, preoperative functional status, American Society of Anesthesiologists Physical Status classification, diabetes, hypertension, gastroesophageal reflux disease, chronic obstructive pulmonary disease, hyperlipidemia, renal insufficiency, dialysis dependency, history of venous thromboembolism, venous stasis, preoperative therapeutic anticoagulation, oxygen dependency, sleep apnea, previous myocardial infarction, previous percutaneous coronary intervention, previous major cardiac surgery, operative time, procedure, anastomotic or staple line leak, and postoperative bleeding

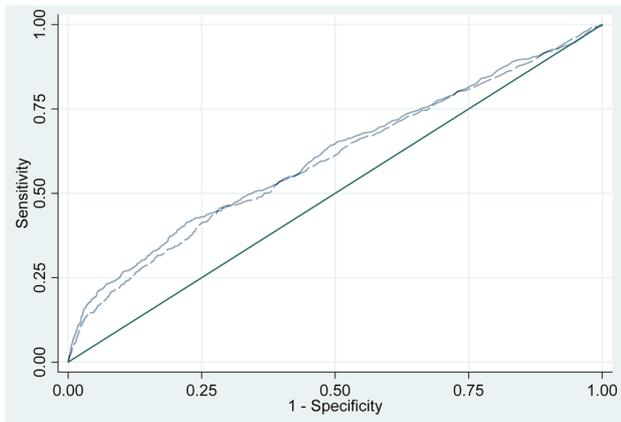
<b>Previous venous thromboembolism</b>	<b>Points</b>	<b>Black race</b>	<b>Points</b>
No	0	No	0
Yes	9	Yes	3
<b>Preoperative functional status*</b>	<b>Points</b>	<b>Operative time (hours)</b>	<b>Points</b>
Independent	0	One point per hour (partial points allowed)	
Partially dependent	1		
Totally dependent	2		
<b>TOTAL SCORE</b> _____			
<b>Risk category</b>	<b>Score</b>	<b>30-day VTE Rate</b>	
Low	<1	< 0.3%	
Medium	1 to 6.9	0.3 to 1%	
High	7 to 9.9	1 to 2%	
Very High	≥ 10	> 2%	

**Fig. 1** Predictive probability for 30-day venous thromboembolism after bariatric surgery. \*Independent: The patient does not require assistance from another person for any activities of daily living. This includes a person who is able to function independently with prosthetics, equipment, or devices. Partially dependent: The patient requires some assistance from another person for activities of daily

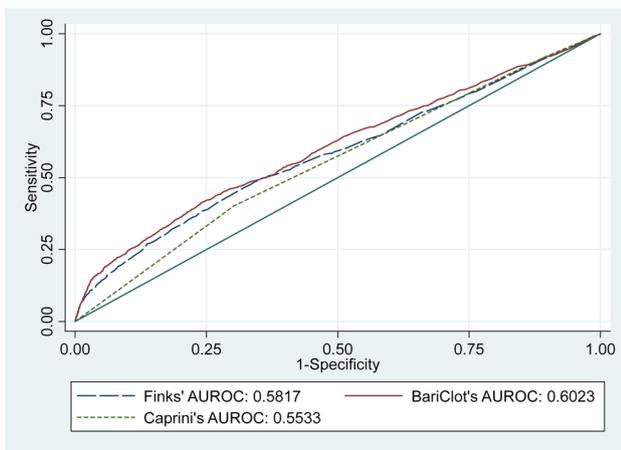
living. This includes a person who utilizes prosthetics, equipment, or devices but still requires some assistance from another person for ADLs. Totally dependent: The patient requires total assistance for all activities of daily living [23]. The *BariClot* tool is available online at <http://www.BariRisk.org>

prophylaxis. For example, the *BariClot* tool defines a person as low-risk as someone without any of the three risk factors and an operative time of < 1 h.

The current ASMBS and American College of Chest Physicians (ACCP) guidelines recommend VTE prophylaxis using mechanical prophylaxis with sequential compression



**Fig. 2** Receiver operating characteristic curve for derivation (solid line) and validation (dashed line) of *BariClot*



**Fig. 3** Receiver operating characteristic curves for *BariClot*, the Michigan Bariatric Surgery Collaborative, and the Caprini predictive risk tools for venous thromboembolism after bariatric surgery

devices (SCDs), low-molecular-weight heparin (LMWH), or unfractionated heparin (UFH) in all bariatric surgery patients [16]. However, the use of only mechanical prophylaxis in low-risk groups may be appropriate. Frantzides [31] found that in low-risk patients, mechanical prophylaxis with early ambulation resulted in less bleeding and VTE. However, this was a single-practice experience with differences in baseline demographics between groups including a higher BMI and operative time in the chemoprophylaxis group. Clements [32] used SCDs, early ambulation and shorter operative times in low-risk patients and found a low VTE rate of 0.41%. Although the quality of these studies is low, there is potential for avoiding chemoprophylaxis in low-risk groups, especially in patients with a higher risk of bleeding. Powering randomized control trials comparing mechanical and chemoprophylaxis for VTE would be exceedingly difficult given its rare incidence in laparoscopic bariatric

surgery, especially considering the population who may benefit from mechanical prophylaxis alone are the lowest risk individuals. The most efficient method of determining the appropriateness of mechanical prophylaxis alone would require databases such as MBSAQIP to record the method of prophylaxis used, so it could be adjusted for in analyses such as those presented in this paper.

In high-risk groups, some have suggested extending chemoprophylaxis up to 21 days [13, 33, 34]. Although there is strong evidence for this approach in cancer patients [35], the evidence in bariatric surgery has not been well established. Raftopoulos [13] investigated a single surgeon's experience and compared in-hospital chemoprophylaxis with extended 10-day chemoprophylaxis and found a significant reduction in rate of VTE with extended therapy (4.5 vs. 0%,  $p=0.006$ , respectively). Another study investigated 3 weeks of LMWH and found a VTE incidence of 0% [33]; however, this study had no comparative control arm. Aminian [36] evaluated the National Surgical Quality Improvement Program (NSQIP) database and found that 83% of VTE occurred after discharge, which suggests that extended prophylaxis may be beneficial. Overall, the evidence for extended prophylaxis is not strong and further trials are needed, particularly among high-risk patients.

Another potential option for high-risk patients is augmented dosing of LMWH. A recent systematic review included three studies with augmented chemoprophylaxis dosing after bariatric surgery [37]. While Scholten et al. [38] found fewer thrombotic events between enoxaparin 30 mg twice a day and 40 mg twice a day (5.4 vs. 0.6%, respectively,  $p < 0.01$ ), two other studies found no significant difference [9, 39]. Bleeding rates were higher with augmented dosing (1.6 vs. 1%) [37].

The *BariClot* tool outperformed the predictive tools by Caprini [19] and Finks [17]. Both of these tools overestimated the probability of VTE. The Caprini tool is designed for different surgical operations and overestimates the risk of VTE in bariatric surgery patients because nearly all patients have an elevated BMI (one point) and an operative time longer than 45 min (two points). This puts patients at a minimum risk of 1% [40]. Further, the Caprini tool predicts risk of VTE without chemoprophylaxis, which reduces its applicability to a population that is routinely given chemoprophylaxis. The most well known surgical risk tool is the American College of Surgeons Risk calculator [41]. This tool is mathematically robust, and elegantly implemented, but is severely restricted given that it is a closed platform [42, 43]. The use of a tool where the calculating algorithms and variables are not openly available is potentially troublesome to the conscientious physician. Further, the restrictive nature of the calculator makes validation on large cohorts impractical. The future of operative risk prediction should lie in open source, transparent, and widely available tools

which can be applied to not only individual patients, but easily validated across different platforms.

A limitation of this work is the lack of data regarding VTE prophylaxis in the MBSAQIP database. This may potentially act as a major confounder if the ASMBS, and MBSAQIP guidelines are not well-adhered to, and hinders our ability to study the effectiveness of mechanical and chemoprophylaxis. MBSAQIP standards require that all centers prescribe postoperative VTE prophylaxis and we can assume unless contraindicated, that the vast majority of patients received VTE prophylaxis. Also, the database does not specify time to VTE diagnoses, a potentially impactful variable in understanding if extended VTE prophylaxis may be beneficial. Finally, rates of VTE that occur after 30 days will not be reported in this study as outcomes are limited to 30 days in the MBSAQIP database, although evidence supports that most VTE events occur within this timeframe [44].

## Conclusions

Bariatric surgery carries a low overall risk of VTE, however, in select populations, the risk is high. Despite the low risk, VTE remains a significant contributor to morbidity and mortality associated with bariatric surgery. Stratifying low- and high-risk populations for VTE after bariatric surgery using the *BariClot* tool allows for informed clinical decision-making and enables further research on different prophylactic measures for low- and high-risk populations.

## Compliance with ethical standards

**Disclosures** Drs. Jerry T. Dang, Noah Switzer, Megan Delisle, Michael Laffin, Richdeep Gill, Daniel W. Birch, and Shahzeer Karmali have no conflict of interest or financial ties to disclose.

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## Affiliations

Jerry T. Dang<sup>1,4</sup>  · Noah Switzer<sup>1</sup> · Megan Delisle<sup>2</sup> · Michael Laffin<sup>1</sup> · Richdeep Gill<sup>3</sup> · Daniel W. Birch<sup>1</sup> · Shahzeer Karmali<sup>1</sup>

Noah Switzer  
nswitzer@ualberta.ca

Megan Delisle  
delislem@myumanitoba.ca

Michael Laffin  
mlaffin@ualberta.ca

Richdeep Gill  
richdeep.gill@ucalgary.ca

Daniel W. Birch  
dbirch@ualberta.ca

Shahzeer Karmali  
shahzeer@ualberta.ca

<sup>1</sup> Department of Surgery, University of Alberta, Edmonton,  
AB, Canada

<sup>2</sup> Department of Surgery, University of Manitoba, Winnipeg,  
MB, Canada

<sup>3</sup> Department of Surgery, University of Calgary, Calgary, AB,  
Canada

<sup>4</sup> Department of Surgery, University of Alberta Hospital,  
University of Alberta, 8440 112 Street NW, Edmonton,  
AB T6G 2B7, Canada